

REMARKS

Claims 17 - 27 are pending. By means of this response, Claims 17- 19 and 24 – 27 are amended. Claims 20 and 23 remain as previously presented. Claims 21 and 22 are cancelled. New claims 41 – 53 are added.

I. Rejections under 35 USC §103

Claims 17, 18, and 20-27 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the '428 patent to Obel et al. (Obel) and the '326 patent to Collins (Collins) in view of the '898 patent to Limousin (Limousin). Claim 19 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Obel, Collins and Limousin as applied to Claim 17 and further in view of the '187 patent to Adams. Applicant respectfully traverses.

In the present application, an apparatus is provided that combines the therapy treatments of cardiac resynchronization and nervous tissue stimulation to improve cardiac performance and efficiency. Among other things, the nervous tissue stimulation of the present application, when titrated to the appropriate levels, will substantially mimic beta-blockers by achieving the desired afterload (blood pressure) as well as preload (volume retention). Thus in amended Claim 17, for example, the nervous tissue stimulation is adjusted based upon monitored physiologic parameters. Importantly, Claim 17 as now amended expressly requires that the electrical stimulation is adjusted based on monitoring of the physiologic parameters during the applied cardiac resynchronization therapy. This feature allows optimization of the pressure-volume relationship, which is not provided by the cited prior art references. Support for the amendments to Claim 17 can be found, for example, at page 8, lines 5 - page 9, line 25, page 11, lines 11-18, in conjunction with Figure 3; page 12, lines 1-2 and lines 18-19; and page 13, lines 1-2.

In Obel, the device provides electrical stimulation controlled by pre-programmed pulse trains, which may also be synchronized to the patient's heart activity,

e.g., start at the beginning of the heart cycle. See col. 4, lines 9 - 20; col. 8, lines 40 - 43. Nothing in Obel's disclosure teaches, suggests, or implies that this electrical stimulation can be adjusted during the delivered pacing therapy as would be required to optimize the pressure-volume relationship. Similarly, the Collins and Limousin references are devoid of the teaching of so adjusting the electrical stimulation. In Collins, the microprocessor generates the characteristics of the neural stimulation pulses according to the timing of codes written to the neural stimulation control bus 22 (pre-determined). See col. 10, lines 22 - 25. Like Obel, these pulses may be synchronized with respect to intrinsic or paced cardiac activity or asynchronous, i.e., according to the operations of an internal timer. See col. 11, lines 36 - 44. However, like Obel, the Collins reference is silent on adjustment of the stimulation during a concurrently applied resynchronization pacing therapy. With regards to Limousin, it is undisputable that the reference is devoid of a disclosure of neural stimulation and thus cannot remedy the deficiencies of the Obel and Collins references.

Accordingly, Applicant respectfully asserts that claim 17 as amended and all claims dependant thereon are patentable over the cited references. Withdrawal of the rejection under 35 U.S.C. § 103(a) of claims 17 – 20 and 23 – 27 as unpatentable over Obel in view of Collins and further in view of Limousin is respectfully requested.

New Claim 41 adds the limitation that delivery of the pacing therapy comprises modifying the parameters of a previously delivered pacing therapy. This limitation is supported at page 8, lines 6 – 11.

New Claim 42 adds the limitation that delivery of the pacing therapy comprises initiating delivery of the pacing therapy. This limitation is supported at page 8, lines 12 – 28.

New Claim 43 adds the limitation that the monitoring means comprises a pressure sensor. This limitation is supported at page 8, line 29 – page 9, line 12, in conjunction with Figure 1C.

New Claim 44 adds the limitation that the monitoring means comprises a pressure sensor adapted for a cardiac location. This limitation is supported at page 8, line 29 – page 9, line 12, in conjunction with Figure 1C.

New Claim 45 adds the limitation that the monitoring means comprises means for determining the patient's diastolic pressure. This limitation is supported at page 9, lines 13 - 20.

New Claim 46 adds the limitation that the monitoring means comprises means for determining the patient's heart rate. This limitation is supported at page 9, lines 13 - 20.

New Claim 47 adds the limitation that the monitoring means comprises means for determining the patient's heart rate variability. This limitation is supported at page 9, lines 13 - 20.

New Claim 48 includes only limitations present in amended claim 17 as discussed above. New claims 49 – 53 include the limitations of new claims 43 – 47, as discussed above. New claims 48 – 53 are believed supported by the specification and allowable over the cited references for the reasons discussed above in conjunction with claims 17 and 43 – 47.

II. Conclusion

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

Should any issues remain outstanding, the Examiner is urged to telephone the undersigned to expedite prosecution.

Respectfully submitted,

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